DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2306. Action to enjoin and restrain the interstate shipment of "Nature's Vegetation." U. S. v. Edgar H. Gremore. Injunction granted. (Inj. No. 82.)

COMPLAINT FILED: On or about March 3, 1945, Eastern District of Wisconsin, against Edgar H. Gremore, Florence, Wis.

NATURE OF CHARGE: That the defendant was engaged in the manufacture, processing, and packing of a product known as "Nature's Vegetation"; that the product consisted essentially of a moist, earthy material containing nitrogenous and carbonaceous material and mineral residues; that the defendant prepared the product from peat from a peat bog on his farm near Florence, Wis.; that for several years he had been packaging and selling the material in interstate commerce; that he had made many consignments of the product in the years 1944 and 1945; that he had sent to certain of these consignees certain circulars separate from the shipments of the product; that the label and circulars represented that the product would cure, prevent, and constitute an adequate treatment for human diseases, such as cancer, heart disease, arthritis, neuritis, eczema, tumors, abscesses, varicose veins, and other human ailments; and that the drug "Nature's Vegetation" had absolutely no therapeutic value in the treatment or prevention of any of the said human diseases. The complaint alleged further that the drug was misbranded as follows:

Section 502 (a), the label of the product bore false and misleading representations;

Section 502 (b) (2), the label failed to bear an accurate statement of the quantity of the contents;

Section 502 (e), the label failed to bear the common or usual name of the article; and,

Section 502 (f) (1), the label failed to bear adequate directions for use.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined during the pendency of the action and after trial permanently enjoined from shipping misbranded drugs in interstate commerce.

DISPOSITION: On March 19, 1945, the court entered a temporary injunction against the defendant. On June 11, 1945, the defendant having failed to answer or otherwise plead to the complaint, the court handed down its findings of fact and conclusions of law, sustaining the allegations in the complaint; and, in accordance therewith, judgment was entered permanently enjoining the defendant from introducing or delivering for introduction into interstate commerce any product or products which were misbranded within the meaning of Sections 502 (a) and 502 (e) of the Act.

2307. Adulteration and misbranding of Holliday's Antiseptic Powder and misbranding of Holliday's Solution #5, Holliday's Cinotol-F, Holliday's Vaginal Ointment, and Holliday's Para Specific. U. S. v. Austin J. Holliday (Holliday's Pharmacal Laboratory). Plea of not guilty. Tried to the court. Verdict of guilty. Imposition of sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 23249. Sample Nos. 49581–H to 49585–H, incl.)

INFORMATION FILED: December 22, 1947, Eastern District of Texas, against Austin J. Holliday, trading as Holliday's Pharmacal Laboratory, Beaumont, Tex.

ALLEGED SHIPMENT: On or about August 21, 1946, from the State of Texas into the State of Louisiana.

PRODUCT: Analyses disclosed that *Holliday's Solution #5* was essentially a sweetened and colored solution of epsom salt; that *Holliday's Cinotol-F* consisted essentially of ferrous iron, potassium bromide, and potassium iodide in solution; that *Holliday's Vaginal Ointment* was a salve having a petrolatum base and containing methyl salicylate and sulfapyridine; that *Holliday's Antiseptic Powder* consisted of salt artificially colored, perfumed with oil of wintergreen, and containing traces of sulfate, aluminum, and some cresolic substance; and that *Holliday's Para Specific* was essentially a solution of potassium bromide, iodide, iron and ammonium citrate, and a small amount of arsenic.

*See also Nos. 2303–2305.

LABEL, IN PART: "Holliday's Solution #5 [or "Cinotol-F," "Vaginal Ointment," "Para Antiseptic Powder," or "Para Specific"] * * * Holliday's Pharmacal Laboratories Los Angeles, Calif."

NATURE OF CHARGE: *Holliday's Solution #5.* Misbranding, Section 502 (a), the label statement "Alkalinity Hydro-Laxative" was false and misleading, since it represented and suggested that the article possessed alkalizing properties, whereas it did not possess such properties; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Holliday's Cinotol-F. Misbranding, Section 502 (a), the label statement "Women" was misleading, since it represented and suggested that the article would be of value in the treatment of female diseases, whereas the article would not be of such value; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the name, quantity, or proportion of potassium bromide, since the label failed to bear a statement of any of the ingredients of the article; Section 502 (f) (2), the article contained potassium bromide, and its labeling failed to bear a warning that a drug containing potassium bromide should not be used by persons with kidney disease, a warning that frequent and continued use of a drug containing potassium bromide may lead to mental derangement, skin eruptions, or other serious defects, and a warning against taking more than the dosage recommended; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Holliday's Vaginal Ointment. Misbranding, Section 502 (a), the label statement "Vaginal" was misleading, since it represented and suggested that the article would be of value in the treatment of conditions affecting women, whereas it would not be of such value; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since its label failed to bear a statement of any of its ingredients.

Holliday's Antiseptic Powder. Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, in that it was represented to be an antiseptic, whereas it was not an antiseptic within the meaning of the law, since it was not a germicide and did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. Misbranding, Section 502 (a), the label statement "Antiseptic Powder" was false and misleading, since the article was not an antiseptic within the meaning of the law; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Holliday's Para Specific. Misbranding, Section 502 (a), the label statement "Specific Blood, Lues, Vitality" was false and misleading, since it represented and suggested that the article would be efficacious in the treatment of syphilis and would furnish vitality to the user, whereas it would not be efficacious in the treatment of syphilis and would not furnish vitality to the user. Further misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the name, quantity, and proportion of potassium bromide and arsenic, since its label failed to bear a statement of any of the ingredients of the article; and, Section 502 (f) (2), the article contained potassium bromide, and its labeling failed to bear a warning that a drug containing potassium bromide should not be used by a person with kidney disease, a warning that frequent and continued use of such drug may lead to mental derangement, skin eruptions, or other serious defects, and a warning against taking more than the dosage recommended.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court on March 16, 1948. The trial was concluded on the same day, with the return of a verdict of guilty, whereupon the court suspended imposition of sentence and placed the defendant on probation for 5 years.